GOVERNMENT OF INDIA
AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH)
LOK SABHA

UNSTARRED QUESTION NO:3988
ANSWERED ON:09.12.2016
Quality of Herbal Medicines
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Will the Minister of AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH) be pleased to state:

Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) the details of research activities in Ayurveda which includes literary and conceptual study, clinical and therapeutic research, drug development including drug standardization during the last three years and the current year;

(b) whether the use of ayurvedic HMPs (Herbal Medicinal Products), can cause lead toxicity and cause conditions like epilepticus, encephalopathy, sensory neural deafness etc., if so, the details thereof along with the preventive steps taken by the Government in this regard;

(c) whether storage conditions can also affect the quality of herbal medicines, which may lead to loss of activity, fungal or bacterial contamination resulting into batch to batch variation;

(d) if so, the steps taken by the Government to ensure the delivery of the same marketed formulation of ayurvedic HMPs; and

(e) whether the Government has any mechanism to keep a check on adulteration of the ayurvedic products, if so, the details thereof?

Answer

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)
(a): The Ministry of AYUSH, Govt. of India has set up Central Council for Research in Ayurvedic Sciences (CCRAS) for undertaking coordinating, developing and promoting research on scientific lines in Ayurveda. The activities are carried out through 30 institute/Centres/Units located all over India. The Council also conduct research through collaborative studies with various universities, hospitals and institutes. The research activities of the council include medicinal plant research (Medico-ethno botanical survey, pharmacognosy and tissue culture), Drug Standardization Pharmacological Research, Clinical Research, Literary Research & Documentation, and other outreach activities.
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The details of activities by CCRAS related to the research during last three years and current year are at Annexure.

(b) to (d): There is a specific category of herbo-mineral or metallic Ayurvedic medicines called Rasaushadies or Rasa yoga. Many of such medicines make use of heavy metals like Mercury, Arsenic and Lead as ingredients after subjecting them to a series of processes called Shodana, Marana, Amritkaram etc. to render them safe and therapeutically effective. Heavy metals in Ayurvedic formulations are not present in free elemental forms but in complex compounds. It is the synergy of various ingredients and use of purification and detoxification techniques that makes the formulation compatible to the body system for therapeutic action with judicious consumption. Permissible limits of heavy metals are defined in the Ayurvedic Pharmacopoeia and are not applicable to Rasaushadhies.

No observations regarding storage conditions have been recorded by the CCRAS.

The Government has issued directions to the States and Central Government Health Scheme (CGHS) to accept supply of Ayurveda, Siddha, Unani And Homoeopathy (ASU&H) medicines with batch wise quality analysis from an approved laboratory/NABL accredited Laboratory.

Good Manufacturing Practices for Ayurveda, Siddha and Unani (ASU) drugs has been made mandatory for license of ASU drugs to ensure storage conditions should be free from fungal or bacterial contamination. In-house quality control section is also made mandatory for batch wise testing facility of ASU products.

(e): The Government of India has defined adulterated drugs under section 33 EE(Chapter IV-A) of the Drugs & Cosmetics Act, 1940.

Under Section 33-I, penalties have been prescribed, for manufacture, sale etc. of Ayurvedic, Siddha or Unani drug in contravention of the Act. State Drug Licensing Authorities are empowered to take action accordingly.

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